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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,315	01/18/2002	Katharine M. Martin	J&J-2086	1178

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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/28/2003 10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/052,315	Applicant(s) MARTIN ET AL.	
	Examiner Shaojia A Jiang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22,24-26 and 28* is/are pending in the application.

4a) Of the above claim(s) *1-16,18 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,19,21,22,24-26 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on May 12, 2003 in Paper No. 9 wherein claims 23 and 27 are cancelled and claims 17, 19, 21-22, 24-26 and 28 have been amended. Currently, claims 1-22, 24-26 and 28 are pending in this application.

This application contains claims 1-16, 18, and 20 drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 17, 19, 21-22, 24-26 and 28 as amended now will be examined on the merits herein.

Applicant's remarks filed on May 12, 2003 in Paper No. 9 with respect to the rejection of claims 17, 19, and 21-28 made under 35 U.S.C. 112 second paragraph for the use of the indefinite expressions, i.e., the term "safe" in claim 17, of record stated in the Office Action dated January 8, 2003 have been fully considered and found persuasive to remove the rejection. Therefore, the said rejection is withdrawn.

Applicant's remarks filed May 12, 2003 in Paper No. 9 with respect to the rejection of claims 17, 19, and 21-28 made under 35 U.S.C. 102(b) as being anticipated by Lion Corp (JP 59181202) for reasons of record stated in the Office Action dated January 8, 2003 have been considered and are found persuasive to remove this particular rejection. Therefore, the said rejection is withdrawn.

Claim Rej ctions - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17, 19, 21-22, 24-26 and 28 are rejected under 35 U.S.C. 112, first paragraph, for lack of enablement, for reasons of record stated in the Office Action dated January 8, 2003.

Applicant's amendment remarks filed May 12, 2003 in Paper No. 9 with respect to this rejection made under 35 U.S.C. 112 first paragraph have been considered but are not deemed to be persuasive to remove the rejection for the following reasons.

As discussed in the previous Office Action January 8, 2003, Applicant's own definition of "regulating the firmness of skin", clearly means regulating the firmness, tone, or texture of skin of a subject or regulating wrinkles in skin of a subject, i.e., preventing the loss of firmness or elasticity of skin, including preventing, retarding, arresting, or reversing the wrinkles in the skin (see page 3 lines 1-20 of the specification). According to the *Wands* factors (see the previous Office Action):

The state of the prior art: The skilled artisan would view that regulating the firmness or tone of skin of a subject or regulate wrinkles in skin of a subject, including preventing, retarding, arresting, or reversing the wrinkles in the skin, are highly unlikely. Over the years many attempts at stopping the aging process have been recorded. However, they have later been proven unsuccessful. There is no fountain of youth. The results of many methods of pharmacological treatments have been uniformly unreliable

and unsatisfactory in regard to preventing, retarding, arresting, or reversing firmness, or tone of skin of a subject or regulate wrinkles in skin of a subject.

The predictability or lack thereof in the art: The skilled artisan would view that regulation of the firmness, tone, or texture of skin of a subject or regulation of wrinkles in skin of a subject, i.e., preventing, retarding, arresting, or reversing the wrinkles in the skin, are highly unpredictable.

The presence or absence of working examples: In the instant case, **no** working examples are presented in the specification as filed showing how to use the herein to regulate the firmness, or tone of skin of a subject herein, or how to prevent, retard, arrest, or reverse the wrinkles in the skin. Applicant's specification provides the experimental results merely showing *in vitro* effects of a hedychium extract (see page 11-15 of the specification).

Genentech, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the *Wands* factors as discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in ***undue experimentation*** to achieve methods of regulating the firmness or tone of skin of a subject or regulate wrinkles in skin of a subject, including preventing, retarding, arresting, or reversing the wrinkles in the skin, with no assurance of success.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 19, 21-22, 24-26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Shiseido Co. Ltd (JP 61291515), for reasons of record stated in the Office Action dated January 8, 2003.

Applicant's remarks filed May 12, 2003 in Paper No. 9 with respect to this rejection of claims 17, 19, and 21-28 made under 35 U.S.C. 102(b) as being anticipated by Shiseido Co. Ltd. in the previous Office have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art for the following reasons.

Applicants assertions that JP 61291515 patent are for treating hot feeling after sunburn, rough skin, razor rash and inflammation, which are not related to skin firmness, tone, or winkles, and that "inherency, however, may not be established by probability or possibilities", and that "the possibility that such composition may regulate the firmness or tone of skin of a subject or regulate wrinkles in skin of a subject is not sufficient for a rejection under 35 U.S.C. 102(b)", have been considered but not found convincing. One of ordinary skill in the art would clearly recognize that sunburn, rough skin, razor rash and inflammation are liable to damage or affect skin firmness, tone, or cause winkles. Hence, the certainty for the inherent treatment herein as one criteria for

determining inherency is clearly seen here, not mere probability or possibilities. The skin of the patient suffering after sunburn, rough skin, razor rash and inflammation would be certainly affected or damaged as to the firmness, tone, or winkles of the skin in that patient.

Thus, as discussed in the previous Office Action, Shiseido's method inherently treats the skin in a subject for regulating the firmness, tone, or texture of skin of a subject or for regulating wrinkles in skin of a subject, as claimed herein since Shiseido's method steps are same as the instant method steps. See *Ex parte Novitski*, 26 USPQ 2d 1389. Thus, Shiseido Co. Ltd anticipates the claimed invention.

In view of the rejections to the pending claims set forth above, no claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
July 15, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER

7/27/03